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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298
7590	08/30/2006			EXAMINER
Lance J. Lieberman, Esq. Cohen, Pontani, Lieberman & Pavane 551 Fifth Avenue, Suite 1210 New York, NY 10176				HANLEY, SUSAN MARIE
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/005,753	SAKAI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Susan Hanley	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 20 March 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 20,22-27,30 and 31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 30 and 31 is/are allowed.

6)  Claim(s) 20, 22-24, 26 and 27 is/are rejected.

7)  Claim(s) 25 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

#### **DETAILED ACTION**

Susan Hanley is now the examiner for this application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2006 has been entered.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 20, 22-27, 30 and 31 are pending and are examined on the merits.

#### ***Election/Restrictions***

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As noted in the previous office action, because a composition comprising a polymethine dye, sulfamic acid as a nitrite reducer (the elected species) and a buffer for maintaining an acidic pH is considered free of the prior art, examination has been extended to other species within the Markush group of claim 20.

#### ***Claim Rejections - 35 USC § 103***

Claims 20-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2) in view of Bates (1961).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain leukocytes. See pages 3 and 4. Mizukami differs from the claims failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 3, lines 42-44. One of ordinary skill in the art clearly would have recognized that methyl amine was suitable for use as a buffer within the pH range (4.5 to 11) described by Mizukami as being useful for the staining reagent disclosed therein. For example, Bates discloses that methyl ammonium (methyl amine/HCl buffer system) and ethylammonium (ethylamine/HCl) can each maintain the pH of an aqueous solution at about 6.1 (p. 345, Table 2, entries 7 and 8 from the bottom). Bates discloses that monoamines are desirable for their ability to effectively maintain pH in the physiological range of 7-9 (p. 341, first paragraph). Recognizing the suitability of methylamine and ethylamine as a buffer in Mizukami's staining reagent, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

#### *Response to Arguments*

All of applicant's argument has been fully considered but is not persuasive of error. Regarding the remaining § 103(a) rejection, applicant argues that the amended claims no longer recite the glutamic acid specie. As such, applicant asserts that neither the primary nor secondary references (Janoff or Dickhardt) disclose or suggest any substance capable of reducing nitrite ions as recited by the presently pending claims.

In response to applicant's argument that Mizukami, Janoff and Dickhardt are no longer relevant together because glutamic acid is no longer recited in the presently pending claims, the new reference,

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Bates, has been applied to the next species, methyl amine and ethylamine. In this case, Mizukami discloses that an acidic buffer is useful in the leukocyte staining polymethine dye-containing compositions disclosed therein. Bates establishes that methylamine and ethyl amine are suitable buffers for use within the pH range set forth by Mizukami. Thus, because Bates establishes that the amine buffer species were known in the art to be useful as buffers at the buffered pH range described by Mizukami, Bates is clearly pertinent to the problem faced by Mizukami.

Claims 30 and 31 are allowed. Claim 25 is objected to as depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley  
Patent Examiner  
1651

Leon B. Lankford Jr.  
Primary Examiner

